Complete Summary

GUIDELINE TITLE

Category IV recording and reporting system. In: Guidelines for the programmatic management of drug-resistant tuberculosis.

BIBLIOGRAPHIC SOURCE(S)

Category IV recording and reporting system. In: World Health Organization (WHO). Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, Switzerland: World Health Organization (WHO); 2008. p. 154-64. [5 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Drug-resistant tuberculosis (DR-TB), including:

- Multidrug-resistant tuberculosis (MDR-TB)
- Extensively drug-resistant TB (XDR-TB)

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Infectious Diseases

INTENDED USERS

Hospitals
Pharmacists
Physicians
Public Health Departments
Utilization Management

GUIDELINE OBJECTIVE(S)

- To describe the information system for Category IV patients, with the objective of recording information needed to monitor program performance and treatment outcomes
- To disseminate consistent, up-to-date recommendations for the diagnosis and management of multidrug-resistant tuberculosis in a variety of geographical, political, economic and social settings
- To enable access to comprehensive, up-to-date, technical and clinical information on the prevention and management of DR-TB and to encourage the implementation of known best practice
- To assist in the development of national policies to improve the diagnosis and management of drug-resistant tuberculosis (DR-TB)

TARGET POPULATION

Patients with drug-resistant tuberculosis

INTERVENTIONS AND PRACTICES CONSIDERED

Management

1. Implement a standard method of recording and reporting in drug-resistant tuberculosis (DR-TB) control programs
2. Use of an expanded section on DR-TB treatment cards for information on patients with human immunodeficiency virus (HIV)
3. Follow International Health Regulations

MAJOR OUTCOMES CONSIDERED

- Time between detection/identification of drug-resistant tuberculosis (DR-TB) and receipt of treatment
- Correlation between laboratory and clinical multidrug-resistant tuberculosis (MDR-TB) reporting

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The nominated lead author for each chapter used a limited evidence retrieval consisting of:

- Personal collection of publications and case reports
- Literatures searches using PubMed and other databases and search engines
- Existing guidelines, both from World Health Organization (WHO) and from other internationally recognized organizations
- Expert consensus during several group meetings for specific topics
- Unpublished data, for example data supplied to the Green Light Committee by their approved multidrug-resistant tuberculosis (MDR-TB) management projects

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The evidence was synthesized by each lead author, but a formal quality assessment was not used. Given the relatively small field of experts in managing drug-resistant tuberculosis, expert opinion was sought from several of the original researchers in the field. The evidence was not formally assessed or graded and there are no formal evidence summaries.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A meeting of the World Health Organization (WHO) Guidelines Steering Group, together with several WHO advisers who had contributed to the 2006 edition, took place in April 2006. It was agreed that there was an urgent need for guidance on the best response to extensively drug-resistant tuberculosis (XDR-TB), based on the emerging evidence. The group identified the chapters to be reconsidered and the gaps to be addressed in this emergency update.

Of the total 18 chapters in the original guideline document, eight have been reviewed and substantially changed in response to the emerging evidence about multidrug-resistant tuberculosis and XDR-TB (chapters 1, 4, 5, 6, 7, 10, 12 and 18). One chapter is new (Chapter 19). The remaining chapters have undergone minor revisions to ensure consistency but have not been rewritten or had any new evidence included.

There was also a decision that a full review of the Guidelines will be started after the emergency update. The WHO Guidelines Review Committee was in place by January 2008 and had already developed draft Guidance for Emergency Guidelines which was used to guide best practice in the finalization of this emergency update.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost is not explicitly considered as part of the recommendations, although the realities of human resources, socioeconomic issues and health system infrastructure are taken into consideration throughout the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The chapters were each reviewed by at least one, and usually several, members of the Guidelines Reference Group, from both within the World Health Organization (WHO) Stop tuberculosis (TB) and human immunodeficiency virus (HIV) departments and outside external experts, as appropriate. One of the expert advisers on the Steering Group was commissioned to harmonize and review all the updated chapters. The remainder of the Steering Group also reviewed the whole document and provided extensive and detailed feedback.

The first draft of the guidelines was reviewed by the Steering Group at meeting held in February 2008. Other advisers at this meeting were Dr Malgosia Grzemska (WHO), Dr Suzanne Hill (WHO), Dr Tim Holtz (CDC, USA) and Dr Kathrin Thomas (WHO). Any outstanding issues were then resolved by e-mail to agree the final

version. Other members of the group were asked to provide reviews at these later stages for particular issues.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Key Changes for the Emergency Update 2008 Compared to the 2006 Guideline

- This guideline has been rewritten to be simpler and more consistent with the directly observed therapy-short course (DOTS) recording and reporting system.
- The treatment card described in this guideline has an expanded section for information on patients with human immunodeficiency virus (HIV).
- Table 1 below provides additional recording and reporting components, which are optional for programmes.
- The International Health Regulations 2005 should be followed.

Key Recommendations (*Indicates updated recommendation)

- A standardized method of recording and reporting should be implemented in drug-resistant tuberculosis (DR-TB) control programmes.
- DR-TB treatment cards should have an expanded section for information on patients with HIV.*
- International Health Regulations should be followed.*

Scope of the Information System

The core information system should be consistent across settings to permit comparison. The forms may be modified as necessary to suit the local context. For instance, additional variables that are considered valuable in specific situations can be included.

The core system does not include all of the detailed information that treatment units may need to manage individual patients; that information should be contained in clinical records and other special forms used in the wards or clinics, and depends on local requirements and practices.

Main Forms/Registers and Flow of Information

See Section 18.4 and Chapter 4 of the original guideline document for a description of the forms and registers and definitions of the patient registration group and treatment outcomes useful for completion of the forms.

Category IV Treatment Card (Form 01)

When the relevant health authority (such as a review panel) decides that a patient should start Category IV treatment, the health staff in the treatment unit should enter the patient in the Category IV Register (see section 18.4.2 of the original

guideline document). The staff should complete the Category IV Treatment Card when the patient is actually starting treatment.

This card is a key instrument for DOT workers who administer drugs to patients on a daily basis. The card should be updated daily by ticking off the supervised administration of drugs. The card represents the primary source of information to complete and periodically update the Category IV Register. The card, or a copy of the card, must always follow the patient (e.g., from a specialized hospital to an ambulatory facility). A copy of the card may be used as a notification form and later also to report the final outcome of treatment. See Section 18.4.1 for a description of the sections of the Category IV Treatment Card.

Category IV Register (Form 02)

The national TB control programme (NTP) should have two TB registers: a District Tuberculosis Register and a Category IV Register. The Category IV Register is the record of all patients who start Category IV treatment (see Chapter 4, section 4.1 of the original guideline document for a general definition of Category IV patients). This register allows quick assessment of the implementation of Category IV, facilitating quarterly reporting and analysis of treatment start and outcomes.

The District Tuberculosis Register is the traditional register used by DOTS programmes in which all TB patients are first registered. In order to integrate the treatment of Categories I, II, III and IV, this register should be modified in three ways:

1. If culture is being done in addition to smear examination in a substantial number of cases, dates of collection and results should be added to both the initial testing and the follow-up areas.
2. Capability to record drug susceptibility testing (DST) should be added, including the date of collection of the sample and the drugs that are being tested.
3. Any patient who is switched to a Category IV regimen because of resistance (without meeting the formal criteria of failure) should have the outcome category "Change to Category IV" entered in the District Tuberculosis Register.

When a patient is starting Category IV treatment, the health staff in the treatment unit should enter the patient in the Category IV Register and indicate in the District Tuberculosis Register that the patient has entered Category IV. The date of registration should be the day when the health staff enters the patient in the Category IV Register. In some countries, it may be the date of the review panel meeting. The Category IV Register should be updated regularly from the Category IV Treatment Card and from the laboratory registers. Patients should be recorded consecutively by their date of registration. There should be a clear separation (extra line) when a new quarter is started.

These guidelines recommend that patients infected with strains with relatively simple resistance patterns (isoniazid [H], isoniazid/streptomycin [HS], isoniazid/ethambutol [HE] and isoniazid/pyrazinamide [HZ]) stay in the District Tuberculosis Register, where adjustment of their regimen should be recorded,

including any second-line agents used (see the National Guideline Clearinghouse [NGC] summary of the World Health Organization [WHO] guideline, Mono-resistant and poly-resistant strains). Patients infected with more complicated mono- and poly-resistance strains (involving R or isoniazid/ethambutol/pyrazinamide [HEZ] resistance) or any mono- and poly-resistant strains that may have developed into multidrug-resistant TB (MDR-TB) should be entered into the Category IV Register.

Some patients started on Category IV regimens may be found to have drug-susceptible disease. Patient in this situation can be removed from Category IV treatment and placed on appropriate first-line therapy. The patient should be crossed out of the Category IV Register (but the name still left legible) and a comment noted in the last column that s/he has drug-susceptible disease. *All patients who are switched should be registered in the District Tuberculosis Register (if they are already registered in the district register, the final outcome should be documented in the original line of registration [do not create a new registration]). These patients do not need to appear in Forms 05, 06 and 07 of the DR-TB reporting forms as they do not have MDR-TB*.

Any patient with mono- or poly resistance whom it has been determined should stay in the DR-TB programme should not be crossed out of the Category IV Register. Whether the patient continues on the same Category IV regimen (often done in programmes using standardized regimens) or gets an individualized regimen based on DST can be documented on the treatment card and the final outcome reported in the Category IV Register. *These patients do not need to appear in Forms 05, 06 and 07 of the DR-TB reporting forms as they do not have MDR-TB*.

See Section 18.4.2 of the original guideline document for a description of the information recorded in the Category IV Register.

Request for Sputum Examination (Form 03)

Form 03 is the same as that recommended for DOTS programmes in the Revised TB recording and reporting forms and registers – version 2006; the upper portion is for requesting smear microscopy, the middle portion for culture and the lower portion for DST; the last section is used for reporting the results. When DST is requested, the registration group should be added. Results should be sent stepwise as they become available.

Laboratory Register for Culture and DST (Form 04)

Laboratories will have separate registers for sputum smear microscopy and culture, while reference laboratories carrying out DST should have additional space in the culture register for DST results (see Form 04). The Laboratory Register for culture and DST should contain samples from all MDR-TB suspects, indicating the registration group (including if positive smear at 3 or 4 months), and be filled in from the request form.

The Laboratory Register should be compared regularly with the Category IV Register to ensure that all confirmed MDR-TB cases are entered in the Category IV Register.

Quarterly Report on MDR-TB Detection and Category IV Treatment Start (Form 05)

This report is used to assess the number of MDR-TB cases detected (distribution and trends) and the number of MDR-TB cases who start treatment. The report should be made quarterly in line with the routines of the NTP. The report should be made by the unit managing MDR-TB. The quarterly report includes:

- The number of patients, with date of result showing MDR-TB during the relevant quarter taken from the Laboratory Register (Form 04). Optionally, the patients could be split by registration group (see Table 1, below).
- The number of MDR-TB patients started on Category IV treatment during the quarter, taken from the Category IV Register (Form 02).

If relevant, the number of XDR-TB cases registered (after cross-checking DST results with type of resistance) and the number of XDR-TB cases started on XDR-TB treatment should be added.

Since there may be a considerable delay between Category IV registration and the start of Category IV treatment, patients who start treatment during the quarter may not be the same as those detected with DR-TB. The information provides an approximation of treatment coverage. These guidelines encourage programmes to calculate the average delay between detection of DR-TB and treatment start (see Table 1, below).

Six-Month Interim Outcome Assessment of Confirmed MDR-TB Cases (Form 06)

Since treatment takes on average two years before final results are known, the TB control programme needs more updated information on treatment outcome. Form 06 can be used to report bacteriological status (negative, positive or no information) of those still on treatment at 6 months, and for those who have already defaulted, died or transferred out, this can be recorded as the final outcome. Bacteriological results are based on the smear and culture data during months 5 and 6 of treatment. Consider the 6-month outcome assessment unknown for a particular patient if a culture or smear result is unknown for either month 5 or 6.

All cases from the Category IV Register should be included in this report.

The form should be completed 9 months after the closing day of the cohort. This allows culture information at month 6 of treatment to be included for all patients in the cohort. For instance, TB patients who started treatment during the first quarter of a year (1 January to 31 March), should have the form filled in from 1 January of the following year.

Annual report of Treatment Result of Confirmed MDR-TB Patients Starting Category IV Treatment (Form 07)

This report is made by the central unit and shows the final result of treatment by year of treatment start. All the patients are classified by previous use of antituberculosis drugs (none, only first-line drugs, also second-line drugs). If

relevant, results for patients with XDR-TB could be added. All data can be extracted from treatment cards and Category IV Register. Form 07 is first completed at 24 months after the last patient in the cohort started treatment. Most of the patients will have finished treatment by 24 months, allowing preliminary assessment of cure rates. Since a few patients may be on treatment for longer than 24 months, the form may be completed again at 36 months, which will then be considered the final result.

Addressing the Backlog of Patients Who Failed Category II Treatment in the Past

When Category IV treatment is being introduced, there may be a large group of patients who are still sputum smear-positive after supervised Category II treatment from previous years. There may also be patients who have received several unsuccessful treatments, are considered incurable by health staff and who have lived with active TB disease with no or inadequate treatment for a period of time. While preparing for Category IV treatment, TB control programmes should keep a list of these patients. When Category IV treatment becomes available, such cases with evidence of active disease should follow the national protocol for Category IV treatment start, ideally having a DST done at the start to confirm MDR-TB.

The number of patients waiting for Category IV treatment should be estimated in all programmes, as this will facilitate planning of drug and other resource needs. As the Category IV treatment programme progresses, the list of chronic cases will become smaller and eventually include only patients who have failed Category IV treatment.

Assuring the Quality of the Recording and Reporting System

In order for the information system for DR-TB to function well, adequate training and supervision are needed. The staff requires basic knowledge of the DOTS information system, with additional training on the specifics of the Category IV forms.

Regular supervisory visits by a central unit to the units using the information system are fundamental to maintain good quality of the information. Regular meetings with staff from different levels may also be very helpful in updating information.

The person responsible for Category IV management should regularly (at least weekly) compare the Category IV Register with the DST register in all the laboratories performing DST to ensure that all patients in whom MDR-TB is diagnosed are started on Category IV treatment. The inclusion of MDR-TB patients from the Laboratory Register should take into consideration the quality of the DST performed in the laboratory. Patients diagnosed with MDR-TB in laboratories without proper quality assurance (i.e. in many private laboratories, the quality of DST is completely unknown) should not be included in the Laboratory Register for Culture and DST (Form 04) until their DST has been confirmed in a qualified laboratory.

Computerized Systems

The recording and reporting system can be managed by hand. However, an electronic system is highly desirable since it facilitates better quality of information as well as data analysis; it will also obviate the need for transcription and repeated entry into different forms. Patient data may be entered in a format similar to the Category IV Treatment Card, and lists similar to the Category IV Register can then be generated. Print-outs of the list may be compared with the handwritten Category IV Register to ensure completeness of the system. The corrected database may then be used to generate quarterly and annual reports.

Even if a computerized system is in place, a handwritten Category IV Register should be maintained, since otherwise corrections cannot be seen.

International Health Regulations (IHR)

The IHR (2005) entered into force on 15 June 2007 and are legally binding upon all WHO Member States. Their purpose and scope are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade." The scope of diseases covered is extremely broad but can include DR-TB. For more information on the IHR (2005) see the WHO web site: http://www.who.int/ihr.

Table 1. Optional Recording and Reporting Component

Some programmes may want to include additional recording and reporting components than those described in this chapter. These guidelines recommend going beyond basic recording and reporting whenever it is feasible and relevant.

Optional indicators and analysis include:

- **MDR-TB treatment coverage**: the proportion of patients started on Category IV treatment among the total number patients detected with MDR-TB during a defined period. This indicator can be calculated from the Quarterly report on MDR-TB detection and Category IV treatment start (Form 05). The same analysis can also be done for XDR-TB.
- **Delay between MDR-TB detection and Category IV treatment start**. This indicator may be analysed separately for each treatment history group and for XDR-TB. This indicator can be calculated from the Laboratory Register for culture and DST (Form 04) and the Category IV Register (Form 02).
- **DST coverage in patient groups targeted for DST**. This assessment requires comparing the number of patients in the target groups for DST. For example, a programme may aim at having all patients who start Category II have DST and, by comparing the names of patients who started Category II with the names in the laboratory register for DST, determine the coverage of obtaining DST in this patient group.
- **The number of failures of Category I treatment**. Routine information from the quarterly reports from most NTP systems.
- **The number of failures of Category II treatment**. Routine information from the quarterly reports from most NTP systems.
- **Percentage of MDR-TB in different patient groups**. This information may be collected from the District TB Registers (if DST data are included), from

the Laboratory Register for culture and DST (Form 04) or through surveys. For example, the percentage of MDR-TB in failures of Category I vs failures of Category II vs default vs relapse.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of a Category IV recording and reporting system

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Foreign Language Translations

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Category IV recording and reporting system. In: World Health Organization (WHO). Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, Switzerland: World Health Organization (WHO); 2008. p. 154-64. [5 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008

GUIDELINE DEVELOPER(S)

World Health Organization - International Agency

SOURCE(S) OF FUNDING

UK Department for International Development
United States Agency for International Development

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All of the above contributors completed a WHO Declaration of Interest form.

The following interests were declared:

Case Gordon declared that he is an unpaid advocate for patients with anti-TB drug resistance and for improved access to high-quality care. He declared that he has himself survived XDR-TB.

Tim Holtz declared that he is an unpaid technical adviser and member of the Scientific Advisory Board of a manufacturer of anti-TB products, to advise on the development of a new anti-TB compound that will be tested in clinical trials of MDR-TB regimens.

Salmaan Keshavjee declared that his employer received funding from a foundation associated with a manufacturer of anti-TB products to support the research and training unit that he is heading.

Carole Mitnick declared that she is serving as a paid member of the Scientific Advisory Board of a manufacturer of anti-TB products, to advise on the development of a new anti-TB compound that will be tested in clinical trials of MDR-TB regimens.

Michael Rich declared that his employer received funding from a manufacturer of anti-TB products, in support of his salary.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in English, Chinese, and French in Portable Document Format (PDF) from the World Health Organization Web site.

Print copies: Available from the WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland; Phone: +41 22 791 3264; Fax: +41 22 791 4857; E-mail: bookorders@who.int.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Executive summary. Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, Switzerland: World Health Organization (WHO); 2008. p. xi-xvi. Electronic copies: Available in Portable Document Format (PDF) from the World Health Organization Web site.

Print copies: Available from the WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland; Phone: +41 22 791 3264; Fax: +41 22 791 4857; E-mail: bookorders@who.int.

In addition, various forms, registers, and reports are available in the appendices of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on September 4, 2009. The information was verified by the guideline developer on December 11, 2009.

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